

Claims

- 5 1. A pharmaceutical composition comprising a DG001 protein and/or a functional fragment thereof, a nucleic acid molecule encoding a DG001 protein and/or a functional fragment thereof and an effector/modulator of said nucleic acid molecule and/or said protein or protein fragment.
- 10 2. The composition of claim 1, wherein the composition contains pharmaceutically acceptable carriers, diluents, and/or additives.
- 15 3. The composition of claim 1 or 2, wherein the nucleic acid molecule is a mammalian DG001 nucleic acid, particularly encoding the human DG001 polypeptide and/or a nucleic molecule which is complementary thereto or a fragment thereof or a variant thereof.
- 20 4. The composition of any one of claims 1 to 3, wherein said nucleic acid molecule is selected from the group consisting of
 - (a) a nucleic acid molecule encoding a polypeptide as shown in SEQ ID NO: 2, or an isoform, fragment or variant of the polypeptide as shown in SEQ ID NO: 2;
 - (b) a nucleic acid molecule which comprises or is the nucleic acid molecule as shown in SEQ ID NO: 1;
 - 25 (c) a nucleic acid molecule being degenerate with as a result of the genetic code to the nucleic acid sequences as defined in (a) or (b),
 - (d) a nucleic acid molecule that hybridizes at 50°C in a solution containing 1 x SSC and 0.1% SDS to a nucleic acid molecule as defined in claim 2 or as defined in (a) to (c) and/or a nucleic acid molecule which is complementary thereto;
 - 30 (e) a nucleic acid molecule that encodes a polypeptide which is at least 85%, preferably at least 90%, more preferably at least 95%, more preferably at least 98% and up to 99,6% identical to the human DG001, as defined in claim 2 or to a polypeptide as defined in (a);
 - 35 (f) a nucleic acid molecule that differs from the nucleic acid molecule of (a) to (e) by mutation and wherein said mutation

causes an alteration, deletion, duplication or premature stop in the encoded polypeptide

- 5 5. The composition of any one of claims 1-4, wherein the nucleic acid molecule is a DNA molecule, particularly a cDNA or a genomic DNA.
6. The composition of any one of claims 1-5, wherein said nucleic acid encodes a polypeptide contributing to regulating the metabolism, in particular human metabolism.
- 10 7. The composition of any one of claims 1-6, wherein said nucleic acid molecule is a recombinant nucleic acid molecule.
8. The composition of any one of claims 1-7, wherein the nucleic acid molecule is a vector, particularly an expression vector.
- 15 9. The composition of any one of claims 1-8, wherein the polypeptide is a recombinant polypeptide.
- 20 10. The composition of claim 9, wherein said recombinant polypeptide is a fusion polypeptide.
11. The composition of any one of claims 1-10, wherein said nucleic acid molecule is selected from hybridization probes, primers and anti-sense oligonucleotides.
- 25 12. The composition of any one of claims 1-11 which is a diagnostic composition.
- 30 13. The composition of any one of claims 1-11 which is a therapeutic composition.
- 35 14. The composition of any one of claims 1-13 for the manufacture of an agent for detecting and/or verifying, for the treatment, alleviation and/or prevention of pancreatic diseases (e.g. diabetes such as insulin dependent diabetes mellitus and/or non-insulin dependent diabetes mellitus), obesity, metabolic syndrome and/or other metabolic diseases

or dysfunctions.

15. The composition of any one of claims 1-14 for the manufacture of an agent for the modulation of pancreatic development.
- 5 16. The composition of any one of claims 1-15 for the manufacture of an agent for the regeneration of pancreatic tissues or cells, particularly pancreatic beta cells.
- 10 17. The composition of any one of claims 1-16 for application in vivo.
18. The composition of any one of claims 1-16 for application in vitro.
- 15 19. Use of a DG001 nucleic acid molecule or a polypeptide encoded thereby or a fragment or a variant of said nucleic acid molecule or said polypeptide and/or an effector/modulator of said nucleic or polypeptide for the manufacture of a medicament for the treatment of pancreatic diseases (e.g. diabetes such as insulin dependent diabetes mellitus and/or non-insulin dependent diabetes mellitus), obesity, metabolic syndrome and/or other metabolic diseases or dysfunctions for controlling the function of a gene and/or a gene product which is influenced and/or modified by a DG001 polypeptide.
- 20 20. Use of a DG001 nucleic acid molecule or use of a polypeptide encoded thereby, or use of a fragment or a variant of said nucleic acid molecule or said polypeptide, or use of an effector/modulator of said nucleic acid molecule or said polypeptide for identifying substances capable of interacting with a DG001 polypeptide in vitro and/or in vivo.
- 25 21. A non-human transgenic animal exhibiting a modified expression of a DG001 polypeptide.
- 30 22. The animal of claim 21, wherein the expression of the DG001 polypeptide is increased and/or reduced.
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23. A recombinant host cell exhibiting a modified expression of a DG001 polypeptide, or a recombinant host cell which comprises a nucleic acid molecule as defined in any one of claims 1 to 7.
- 5 24. The cell of claim 23 which is a human cell.
25. A method of identifying a (poly)peptide involved in the regulation of energy homeostasis and/or metabolism in a mammal comprising the steps of
- 10 (a) contacting a collection of (poly)peptides with a DG001 homologous polypeptide or a fragment thereof under conditions that allow binding of said (poly)peptides;
- (b) removing (poly)peptides which do not bind and
- (c) identifying (poly)peptides that bind to said DG001 homologous polypeptide.
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26. A method of screening for an agent which effects/modulates the interaction of a DG001 polypeptide with a binding target comprising the steps of
- 20 (a) incubating a mixture comprising
- (aa) a DG001 polypeptide or a fragment thereof;
- (ab) a binding target/agent of said DG001 polypeptide or fragment thereof; and
- (ac) a candidate agent under conditions whereby said polypeptide or fragment thereof specifically binds to said binding target at a reference affinity;
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- (b) detecting the binding affinity of said DG001 polypeptide or fragment thereof to said binding target to determine an affinity for the agent; and
- 30 (c) determining a difference between affinity for the agent and reference affinity.
27. A method for screening for an agent, which effects/modulates the activity of a DG001 polypeptide, comprising the steps of
- 35 (a) incubating a mixture comprising
- (aa) a DG001 polypeptide or a fragment thereof; and
- (ab) a candidate agent

under conditions whereby said DG001 polypeptide or fragment thereof exhibits a reference activity,

- (b) detecting the activity of said DG001 polypeptide or fragment thereof to determine a activity for the agent; and
- (c) determining a difference between activity for the agent and reference activity.

28. A method of producing a composition comprising the (poly)peptide identified by the method of claim 25 or the agent identified by the method of claim 26 or 27 with a pharmaceutically acceptable carrier and/or diluent.
29. The method of claim 28 wherein said composition is a pharmaceutical composition for preventing, alleviating or treating of diseases and disorders, including pancreatic diseases (e.g. diabetes), obesity, and/or metabolic syndrome.
30. Use of a (poly)peptide as Identified by the method of claim 25 or of an agent as identified by the method of claim 26 or 27 for the preparation of a pharmaceutical composition (i) for the treatment, alleviation and/or prevention of pancreatic diseases (e.g. diabetes), obesity, and/or metabolic syndrome, (ii) for the modulation of pancreatic development and/or (iii) for the regeneration of pancreatic cells or tissues.
31. Use of a nucleic acid molecule as defined in any one of claims 1 to 7 or 11 for the preparation of a medicament for (i) the treatment, alleviation and/or prevention of diseases or dysfunctions, including pancreatic diseases (e.g. diabetes), obesity, and/or metabolic syndrome, (ii) for the modulation of pancreatic development and/or (iii) for the regeneration of pancreatic cells or tissues.
32. Use of a polypeptide as defined in any one of claims 1 to 6, 8 or 9 for the preparation of a medicament for (i) the treatment, alleviation and/or prevention of pancreatic diseases (e.g. diabetes), obesity, and/or metabolic syndrome, (ii) for the modulation of pancreatic development and/or (iii) for the regeneration of pancreatic cells or tissues.

- 5 33. Use of a vector as defined in claim 7 for the preparation of a medicament for (i) the treatment, alleviation and/or prevention of pancreatic diseases (e.g. diabetes), obesity, and/or metabolic syndrome, (ii) for the modulation of pancreatic development and/or (iii) for the regeneration of pancreatic cells or tissues.
- 10 34. Use of a host cell as defined in claim 23 or 24 for the preparation of a medicament for (i) the treatment, alleviation and/or prevention of pancreatic diseases (e.g. diabetes), obesity, and/or metabolic syndrome, (ii) for the modulation of pancreatic development and/or (iii) for the regeneration of pancreatic cells or tissues.
- 15 35. Use of a DG001 nucleic acid molecule or of a fragment thereof for the production of a non-human transgenic animal which over- or under-expresses the DG001 gene product.
- 20 36. A method for increasing Insulin production in a cell comprising:
i) stimulating DG001 expression in said cell, and/or
ii) introducing DG001 or a DG001 effector/modulator into said cell.
37. The method of claim 36 further comprising the step of differentiating said cell into a beta-like cell.
- 25 38. A cell preparation obtained or obtainable by the method of claim 36 or 37.
- 30 39. Kit comprising at least one of
(a) a DG001 nucleic acid molecule or a functional fragment or an isoform thereof;
(b) a DG001 amino acid molecule or a functional fragment or an isoform thereof;
(c) a vector comprising the nucleic acid of (a);
(d) a host cell comprising the nucleic acid of (a) or the vector of (c);
(e) a polypeptide encoded by the nucleic acid of (a), expressed by the vector of (c) or the host cell of (d);
35 (f) a fusion polypeptide encoded by the nucleic acid of (a) or the vector of (c);

- (g) an antibody, an aptamer or another effector/modulator against the nucleic acid of (a) or the polypeptide of (b), (e), or (f) and /or**
- (h) an anti-sense oligonucleotide of the nucleic acid of (a).**